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No. 06-1249

IN THE
Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

ON WRIT OF CERTIORARI
TO THE SUPREME COURT OF VERMONT

BRIEF OF *AMICI CURIAE* MEMBERS OF CONGRESS IN SUPPORT OF RESPONDENT

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BRIEF OF *AMICI CURIAE* MEMBERS OF CONGRESS IN SUPPORT OF RESPONDENT

INTEREST OF *AMICI CURIAE*

The question presented in this case is whether to discard the well-settled understanding of Congress, courts around the country, and (until quite recently) the federal Food and Drug Administration ("FDA") that the Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. § 301, *et seq.* does not preempt state-law failure-to-warn claims.

This brief is submitted on behalf of Senators Patrick J. Leahy, Edward M. Kennedy, Sheldon Whitehouse, Tom Harkin, Dianne Feinstein, Richard J. Durbin, Bernard Sanders, Russell D. Feingold, Representatives Henry A. Waxman, John Conyers, Jr., John D. Dingell, Frank Pallone, Jr., Bart Stupak, Zoe Lofgren, Linda Sánchez, Debbie Wasserman Schultz, Maxine Waters, and Peter Welch.

Amici curiae are Members of Congress with an important interest in this issue.[1] *Amici* include the Chairmen of the United States Senate and House Committees on the Judiciary, the Chairman of the Senate Committee on Health, Education Labor, and Pensions, the Chairman of the House Committee on Energy and Commerce, the Chairmen of the Subcommittee on Health and the Subcommittee on Oversight and Investigations of the House Committee

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[1] This brief has been filed with the written consent of the parties, which is on file with the Clerk of Court. No counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amici* or their counsel, make a monetary contribution to the preparation or submission of this brief.

on Energy and Commerce, and the Chairman of the House Committee on Oversight and Government Reform, as well as Members of these Committees. *Amici* have extensive experience in federal pharmaceutical regulation and federal preemption issues under the FDCA. *Amici* have participated in numerous legislative proceedings concerning FDCA preemption, most recently in the context of the Food & Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823 (2007). *Amici* have conducted public hearings on the preemption issue, such as *Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?* Hearing Before the Senate Committee on the Judiciary, 110th Cong. 1st Sess. (Sept. 12, 2007) (hereafter "*Senate Regulatory Preemption Hearing*"), and *Should FDA Drug and Medical Device Regulation Bar State Liability Claims?* Hearing Before the House Committee on Oversight and Government Reform, 110th Cong. 2d Sess. (May 14, 2008) (hereafter "*House FDA Preemption Hearing*").

At bottom, this case presents a question of congressional intent. This Court has explained that "[t]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996) (citation and internal quotation marks omitted); *see also Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 516 (1992) (same). *Amici* are uniquely situated to address the question of congressional intent at the center of this case. Although *amici* submit this brief in their individual capacities, not on behalf of Congress itself, their views are informed by their experiences as Members of Congress.

SUMMARY OF ARGUMENT

At its core, "[p]re-emption fundamentally is a question of congressional intent." *English v. General Elec. Co.,* 496 U.S. 72, 78 (1990). Petitioner Wyeth ascribes to Congress a considered judgment to displace state tort remedies and strip consumers of their right to receive compensation for injuries caused by inadequate warnings on the part of drug manufacturers. But Congress has made no such judgment.

To the contrary: when Congress enacted the FDCA 70 years ago, it deliberately preserved state-law damages claims. Since that time, Congress has consistently understood that federal law does not preempt state-law failure-to-warn claims with respect to drugs approved by the FDA. This understanding has been fortified by settled practice under the statute. For decades, innumerable state-law actions involving FDA-approved pharmaceuticals have been prosecuted to final judgment or settlement. The courts and (until recently) the FDA have shared Congress' view that federal labeling rules create only minimum requirements and do not immunize drug companies from liability under state law. The widespread practice of permitting state-law claims, coupled with a common understanding of the statute's meaning among the courts, Congress, and the FDA, has created precisely the kind of "well-embedded [statutory] interpretation" that this Court has held is entitled to respect. *CBOCS West, Inc. v. Humphries*, 128 S.Ct. 1951, 1958 (2008).

In this case, the FDA has advanced a radical new legal position regarding the preemptive effect of the FDCA that represents a sharp break from the

practice of the past 70 years. The FDA now asserts that the Act displaces state failure-to-warn claims for federally approved drugs. This revolutionary change would bar the kind of traditional state-law actions that have been brought for decades under the FDCA.

Moreover, the agency's changed view represents a usurpation of authority properly belonging to Congress, the States, and the courts. The FDA would arrogate to itself the power to decide the preemptive force of the federal statute, which is a matter of congressional (and not administrative) intent. Whatever the FDA's view of its labeling regulation, *Congress* never intended to allow the FDA to adopt regulations that would preempt failure-to-warn lawsuits under state law. It is *congressional* intent, not FDA intent, that governs the preemption inquiry.

An agency cannot supplant Congress. As Justice Scalia has noted, "[a]gencies may play the sorcerer's apprentice but not the sorcerer himself." *Alexander v. Sandoval,* 532 U.S. 275, 291 (2001). The FDA's attempt to expand the preemptive scope of the regulatory scheme is nothing short of an illegitimate power grab. The FDA's position poses a threat not merely to injured consumers and the States, but also to the separation of powers and the constitutionally assigned role of Congress in our system of government.

Altering the construction of the FDCA at this late date would also frustrate congressional intent and impair the statutory system of federal prescription drug regulation. Far from standing "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," state-law claims against pharmaceutical manufacturers

"necessarily perform an important remedial role in compensating" injured individuals and in encouraging drug safety. *Sprietsma v. Mercury Marine,* 537 U.S. 51, 64 (2002) (internal citations omitted). State tort law complements federal drug regulation by not only compensating those injured by misconduct but also by deterring future harm.

There are important reasons for holding that FDA approval of a drug label does not preempt state-law failure-to-warn claims. Manufacturers should be given the incentive to supply the FDA with the most current evidence so that labels reflect the best scientific information. Congress understands that state tort law is an indispensable partner to federal safety regulation.

As Senator Specter has commented,

> If state law is preempted and lawsuits or claims are dismissed, public safety and health may be affected. In the past, some tort cases have unearthed industry secrets and safety shortcuts that manufacturers have taken. Information obtained in tort suits has turned out to be very useful to regulators seeking to protect the public. In addition, the unearthing of this information has caused manufacturers to improve the safety of their products, or make other changes that protect the public.

Senate Regulatory Preemption Hearing at 133-34.

In addition, the FDA lacks the administrative resources to safeguard drug safety without the assistance of state-court lawsuits. The agency has suffered from politicization and a bias favoring

approval of new pharmaceuticals rather than ensuring the safety of the 11,000 drugs already on the market. As Senator Grassley has observed: "There's enough of a pattern of problematic drugs to ask for an independent review of how the FDA follows up on the effects of medicines that it's approved."[2] One of FDA's own scientific advisory committees has concluded that the agency has "serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." FDA Subcommittee on Science & Technology, *FDA Science & Mission at Risk* 2-3 (Nov. 2007) ("*FDA Science & Mission at Risk*").

For all these reasons, this Court should hold that the FDCA does not preempt state-law failure-to-warn claims.

ARGUMENT

This Court has instructed that preemption analysis must begin with a healthy presumption against displacement of state law: "In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Lohr,* 518 U.S. at 485 (citation, internal quotation marks, and alterations omitted). That starting assumption is fortified in this case by well-settled expectations regarding the impact of the FDCA on state law.

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[2] Associated Press, "FDA's Review Process Under Investigation," Mar. 4, 2008 (available at http://ahrp.blogspot.com/2008/03/gao-to-investigate-fda-review-process.html).

Since the FDCA was enacted in 1938, Congress, the courts, and the FDA have operated with a shared understanding that FDA approval of a drug label does not preempt state-law failure-to-warn claims.

A. The History of the FDCA Confirms That It Does Not Preempt Failure-to-Warn Claims.

Federal drug labeling regulation began with the Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), codified at 21 U.S.C. §§ 1-15 (1934) (repealed in 1938 by 21 U.S.C. § 329(a)). Prior to 1906, "the States provided the primary and possibly the exclusive source of regulatory control over the labeling of foods and drugs." *In re Vioxx Prods. Liab. Litig.,* 501 F. Supp. 2d 776, 782 (E.D. La. 2007). State courts recognized common-law causes of action for negligence with respect to medicines and related products.[3]

Nothing in the Pure Food and Drug Act of 1906 displaced traditional state-law tort remedies. The Act was part of the progressive agenda of the trust-busting reformer, Theodore Roosevelt,[4] and it was intended solely to protect consumers – not to deny

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[3] *See, e.g., Boyd v. Coca Cola Bottling Works,* 177 S.W. 80, 81 (Tenn.1915); *Willson v. Faxon, Williams & Faxon*, 208 N.Y. 108, 112, 101 N.E. 799, 801 (1913); *Blood Balm Co. v. Cooper*, 83 Ga. 457, 10 S.E. 118, 119 (1889); *Thomas v. Winchester,* 2 Seld. 397, 1852 WL 4748 (N.Y.1852); *Fleet v. Hollenkemp*, 52 Ky. (1 B. Mon.) 219, 220 (1852).

[4] *See* Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, § 3, 34 Stat. 768, 768–69, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 201(d), 52 Stat. 1040, 1040 (codified in scattered sections of 21 U.S.C.).

state tort remedies to victims of defective drugs.[5] For example, in 1913, this Court considered the effect of a 1907 Wisconsin statute providing that mixtures or syrups offered for sale "shall have upon them no designation or brand ... other than that required by the state law." *McDermott v. Wisconsin,* 228 U.S. 115, 127 (1913). Although this Court held that Wisconsin could not require that federally approved labels "shall be removed from the packages," the Court also "[c]onced[ed] to the state the authority to make regulations consistent with the Federal law for the further protection of its citizens against impure and misbranded food and drugs." *Id.* at 133.

In 1938, after the deaths of more than 100 people from elixir of sulfanilamide, Congress enacted the FDCA, which prohibited false therapeutic claims and for the first time required FDA premarket notification for drugs. As this Court has long recognized, the purpose of the statute was to increase consumer protection. *See United States v. Dotterweich,* 320 U.S. 277, 280, 282 (1943) ("The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection").

Congress considered including in the Act a private federal cause of action for damages caused by faulty or unsafe products. *See* H.R. Rep. No. 73-6110,

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[5] Dennis R. Johnson, *The History of the 1906 Pure Food and Drugs Act and the Meat Inspection Act*, 37 FOOD DRUG COSM. L.J. 5, 8–9 (1982); Richard Curtis Litman & Donald Saunders Litman, *Protection of the American Consumer: The Muckrakers and the Enactment of the First Federal Food and Drug Law in the United States*, 36 FOOD DRUG COSM. L.J. 647, 648–51 (1981).

pt. 1, § 25 (1933) ("Liability for Personal Injuries - a right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act."). Notably, the Senate deleted this proposed private cause of action from the bill on the ground that it was unnecessary because "[a] common-law right of action exists" under state law. *Hearing on S. 1944 Before a Subcomm. of the Comm. on Commerce*, 73d Cong., 2d Sess. 400, 403 (1933). *See also Consumer Fed'n of Am. v. Upjohn,* 346 A.2d 725, 731 (D.C. 1975) (explaining that private right of action was omitted from bill because "it would create an *unnecessary* federal action *duplicative of state remedies*" and concluding that Congress "*rejected* [] setting up a nationally uniform law for such" actions) (emphasis added); Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok,* 59 MO. L. REV. 895, 924 & n.130 (1994) ("Congress rejected a provision in a draft of the original FD&C Act providing a federal cause of action for damages [for injuries caused by prescription drugs] because 'a common law right of action [already] exists.'").

Congress' assumption that state-law causes of action would remain under the FDCA – coupled with its decision not to provide a federal remedy – is strong evidence that it did not mean to displace traditional state tort actions. Where Congress displaces state law, it typically provides an alternative federal remedy.[6] As the Court has

[6] *See, e.g.*, 42 U.S.C. § 2210 (Price-Anderson Act); 42 U.S.C. §§ 300aa-10 to 300aa-34 (National Vaccine Injury Compensation Program); 49 U.S.C. § 40101 (Supp. 2004) (Air Transportation Safety and System Stabilization Act of 2001, also known as the

acknowledged, "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates v. Dow Agrosciences LLC,* 544 U.S. 431, 449 (2005). *See also Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238, 251 (1984) ("This silence [of Congress in enacting and amending the Atomic Energy Act] takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

B. Congress Confirmed Its Understanding In a Series of Amendments To The FDCA.

Congress continued to assume the availability of state-law causes of action in revisiting the FDCA in a series of amendments over the past half-century.

Congress enacted the landmark Kefauver-Harris amendments to the FDCA in 1962, which strengthened pharmaceutical regulation and added further protections for consumers. The purpose of the legislation was "to strengthen and broaden existing laws in the drug field so as to bring about better, safer, medicine and to establish a more effective system of enforcement of the drug laws." S. Rep. No. 87-1744, 87th Cong., 2d Sess. 1 (1962). The catalyst of the reforms was the thalidomide tragedy in Europe in the late 1950s and early 1960s, in which thousands of children were born with birth defects. Institute of

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September 11th Victim Compensation Fund); 29 U.S.C. § 1144 (Employee Retirement Income Security Act of 1974).

Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 22, 152 (Alina Baciu, Kathleen Stratton & Shelia P. Burke, eds. 2007) ("IOM Report").

The 1962 Amendments "shifted the burden of proof from FDA (which previously had to prove harm to keep a drug from being marketed) to manufacturers, who now were required to demonstrate both safety and efficacy prior to receipt of marketing approval." IOM Report, *supra*, at 152 (citation omitted). Even with these reforms, the "FDA's ability to form judgments about the safety and efficacy of drugs depends upon the submission of data, usually from drug company sponsors, rather than on the use of data developed independently or on its own initiative." *Id.*

The 1962 Amendments also clarified the FDCA's effect on state law. Congress included language limiting the potential preemptive effect of the FDCA to cases of "direct and positive conflict": "Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a *direct and positive conflict* between such amendments and such provision of State law." Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) (emphasis added). The plain language of this provision makes clear that the Amendments do not preempt state law in the absence of such a "direct and positive" conflict.

In contrast, when Congress has wished to preempt state law in the FDCA, it has done so clearly. For example, Congress has enacted an

express preemption provision for medical devices. *Riegel v. Medtronic, Inc.,* 128 S.Ct. 999 (2008) (considering the effect of the express preemption provision of the Medical Device Amendments of 1976, 21 U.S.C. § 360(k)(a)). Although many Members of Congress do not agree with the construction of the Medical Device Amendments adopted by the Court in *Riegel*,[7] that decision does not govern this case because there is no express preemption for drugs in the FDCA.

Further confirming the absence of preemption in this case are the express *anti*-preemption provisions for nonprescription or "over-the-counter" ("OTC") drugs, FDCA Section 751, 21 U.S.C. § 379r, and for the labeling and packaging of cosmetics, FDCA Section 752, 21 U.S.C. § 379s. These provisions prohibit any State or political subdivision from establishing or continuing "any requirement" relating to the regulation of an OTC drug or the labeling or packaging of a cosmetic that is "different from or in addition to, or that is otherwise not identical with," a requirement under the FDCA, the Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1471 *et seq.*, or the Fair Packaging and Labeling Act, 15 U.S.C. § 1451 *et seq. See* 21 U.S.C. §§ 379r(a), 379s(a). However, the OTC and cosmetic anti-preemption provisions expressly exempt state product liability actions from federal displacement: "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. §§

[7] Legislation to reverse the *Riegel* decision has been introduced in both the House and the Senate. *See* S. 3398, 110th Cong.; H.R. 6381, 110th Cong.

379r(e), 379s(e). Thus, although Congress has provided for some degree of preemption for state requirements regarding OTC drugs and cosmetics labeling, it has specifically preserved state-law products liability actions.

The statutory framework demonstrates Congress' clear understanding of the potential for state-law products liability actions against manufacturers of medical devices, OTC drugs, and cosmetics. The absence of any analogous express preemption provision for prescription drugs is significant: "[i]f Congress wants to take the extraordinary step of giving drug manufacturers immunity from personal tort actions, it would expressly state such intentions whether by statute or legislative history." *Merrell Dow Pharms., Inc. v. Oxendine,* 649 A.2d 825, 829 (D.C. 1994) (quoting *Kociemba v. G.D. Searle & Co.,* 680 F. Supp. 1293, 1299-1300 (D. Minn.1988) (ruling that FDCA did not preempt state tort law actions against manufacturers of prescription drugs)).

Moreover, the relationship between OTC and prescription drugs makes the lack of an express preemption provision for prescription drugs even more significant. Some OTC drugs are initially approved as prescription drugs under the FDCA and are "switched over" to OTC status after several years of marketing, as in the cases of Claritin and Zyrtec. Thus, a drug initially receiving FDA approval may later become an OTC drug governed by Section 751, which explicitly contemplates products liability claims under state law. It is implausible to suggest that Congress silently created immunity through federal preemption for prescription-drug-related claims but then affirmatively negated that immunity

when the same drug became OTC. Rather, it is plain that Congress has always assumed that the fact of FDA approval would not preclude state-law product liability actions.

Other provisions of the FDCA also acknowledge Congress' understanding of drug company failure-to-warn liability. For example, Section 756 of the FDCA provides that certain safety reports to FDA may not be considered admissions for liability purposes. 21 U.S.C. § 379v (manufacturer's submission of a safety or adverse event report is not "an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness"). This provision indicates a congressional recognition of the potential for state tort suits, because its evident purpose is to prohibit the use of safety reports in product liability litigation.

In addition, in the National Vaccine Injury Compensation Program ("VICP"), Congress provided an administrative remedy for vaccine-related injuries as an alternative to state tort liability, with the possibility of an opt-out to state court if the injured person wishes to pursue a state-law products liability remedy. 42 U.S.C. § 300aa-21(a). Vaccines are approved under the Public Health Service Act, 42 U.S.C. § 300aa-1 to -6, but otherwise regulated as drugs. *E.g.*, 21 C.F.R. § 600 *et seq.* VICP quite clearly confirms Congress' understanding that FDA regulation of a drug does not preempt state-law tort liability.

Given the statutory structure, "[c]ourts have generally rejected the argument that the FDA labeling approval process somehow preempts state

law adequacy of warning claims." *In re Zyprexa Prods. Liab. Litig.,* 489 F.Supp.2d 230, 273 (E.D.N.Y. 2007). Innumerable cases have proceeded to final judgment or settlement on the widespread understanding that FDA approval does not bar state failure-to-warn claims. The traditional view is that "approval by the FDA of the language involved is *not necessarily* conclusive on the question of the adequacy of the warnings." *Brochu v. Ortho Pharm. Corp.,* 642 F.2d 652, 658 (1st Cir. 1981) (emphasis in original; citation omitted). "[C]ompliance with federal laws and regulations concerning a drug, though pertinent, does not in itself absolve a manufacturer of liability." *Salmon v. Parke, Davis & Co.,* 520 F.2d 1359, 1362 (4th Cir. 1975). In *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 815-16 & n.13 (1986), this Court encountered a state-law negligence per se claim premised on a violation of the FDCA. *See also Yarrow v. Sterling Drug, Inc.*, 263 F.Supp. 159, 162 (D.S.D. 1967), *aff'd*, 408 F.2d 978 (8th Cir. 1969) (imposing liability "[a]lthough all of the government regulations and requirements have been satisfactorily met in the production and marketing of [the drug], and in the changes made in the literature"); *Stromsodt v. Parke-Davis & Co.*, 257 F.Supp. 991, 997 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969) ("Although all of the Government regulations and requirements had been satisfactorily met in the production and marketing of Quadrigen, the standards promulgated were minimal. The Defendant still owes a duty to warn of dangers of which it knew or should have known in the exercise of reasonable care."); *Stevens v. Parke, Davis & Co.*, 9 Cal.3d 51, 65, 107 Cal.Rptr. 45, 53, 507 P.2d 653, 661 (1973) ("The warnings required

by such [regulatory] agencies may be only minimal in nature and when the manufacturer or supplier knows of, or has reason to know of, greater dangers not included in the warning, its duty to warn may not be fulfilled."); *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038 (Kan.), *cert. denied*, 469 U.S. 965 (1984) (imposing liability for compensatory and punitive damages based on failure to make a disclosure even though FDA expressly rejected a similar disclosure, proposed by a manufacturer of a competing version of same product); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 534 (Ore. 1974) ("We hold that the warnings given by an ethical drug manufacturer may be found inadequate," despite FDA approval).[8]

As a former Commissioner of the Food and Drug Administration has written:

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[8] *See also Desiano v. Warner-Lambert Co.,* 467 F.3d 85, 97 & n.9 (2d Cir.2006). *aff'd*, 128 S.Ct. 1168 (2008); *Tobin v. Astra Pharm. Prods., Inc.,* 993 F.2d 528, 537-38 (6th Cir.1993); *Hill v. Searle Labs.,* 884 F.2d 1064, 1068 (8th Cir.1989); *Wells v. Ortho Pharm. Corp.,* 788 F.2d 741, 745-46 (11th Cir.1986); *Alman Bros. Farm & Feed Mill, Inc. v. Diamond Laboratories, Inc.*, 437 F.2d 1295 (5th Cir.1971); *Perry v. Novartis Pharm. Corp.,* 456 F.Supp.2d 678, 685 (E.D.Pa.2006); *Adesina v. Aladan Corp.,* 438 F.Supp.2d 329, 337-38 (S.D.N.Y.2006); *Witczak v. Pfizer, Inc.,* 377 F.Supp.2d 726, 731-32 (D.Minn.2005); *Caraker v. Sandoz Pharm. Corp.,* 172 F.Supp.2d 1018, 1033 (S.D.Ill.2001); *Motus v. Pfizer, Inc.,* 127 F.Supp.2d 1085 (C.D.Cal.2000); *Jones by Jones v. Lederle Labs.,* 695 F.Supp. 700, 709-11 (E.D.N.Y.1988); *Stephens v. G.D. Searle & Co.,* 602 F.Supp. 379, 382 (E.D.Mich.1985); *Savina v. Sterling Drug, Inc.,* 795 P.2d 915, 931 (Kan.1990); *MacDonald v. Ortho Pharm. Corp.,* 394 Mass. 131, 475 N.E.2d 65, 70-71 (1985); *Seley v. G. D. Searle & Co.*, 423 N.E.2d 831, 837 (Oh.1981); *Edwards v. Basel Pharm.,* 933 P.2d 298, 302 (Okla.1997).

> Nothing in the statutes the FDA administers suggests that they oust state damages actions for pharmaceutical products. No appellate court, before or after the advent of the FDA, has held that a state-law failure-to-warn claim for a prescription drug is preempted by federal law. And Congress has not acted to preempt or limit state damage actions, even though it has long been aware of tort litigation over drug products . . . .

David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims,* 96 GEO. L.J. 461, 462 (2008).

The same view of non-preemption is reflected in the recently enacted Food & Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823 (2007). The Act does not contain any express preemption provision barring state-law damages claims. The sole preemption language included in the FDAAA precludes states and their political subdivisions from "establish[ing] or continu[ing] in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database," 42 U.S.C. § 282(d), a provision that is not relevant to the instant case.

In enacting the FDAAA, Congress, for the first time, gave FDA the authority to require certain labeling changes. In so doing, however, Congress rejected a Senate proposal sought by pharmaceutical companies that would have required FDA to pre-approve all changes to drug labels – a proposal that might have given drug companies an argument against state tort suits alleging that they wrongly

failed to issue voluntary warnings.[9] Instead of such a provision, Congress adopted a "Rule of Construction" providing that FDA's new labeling change authority "shall not be construed to affect the responsibility" of the manufacturer "to maintain its label in accordance with existing responsibilities, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations)." The cited regulations establish a mechanism for drug manufacturers to provide up-to-date safety information to physicians and patients, even without prior FDA approval. Members of Congress made clear that, in giving FDA the power to order a labeling change, the FDAAA did not alter a manufacturer's longstanding responsibility promptly to update product labels with safety information at the earliest possible moment – without waiting for FDA to approve the change.[10] The statements also

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[9] S. 1082, 110th Cong., 1st Sess. § 208 (proposing new § 506D to FDCA).

[10] As Rep. Waxman explained, "in giving FDA this labeling change authority, Congress is making it clear that we do not intend to impact a drug company's responsibility to promptly update its label with safety information on its own accord." 153 Cong.Rec. H10596 (Sept. 19, 2007) (statement of Rep. Waxman). *Accord*, 153 Cong.Rec. S11833 (Sept. 20, 2007) (statement of Sen. Kennedy) ("Congress has stated very clearly in the legislation that we do not intend the new authority being given to FDA to preempt common law liability for a drug company's failure to warn its customers of health risks."); *id.* at S11834 (statement of Sen. Leahy) ("The legislation we are set to pass today contains a rule of construction making clear that Congress has again decided that we are not preempting State law regarding the responsibility of drug manufacturers to immediately notify consumers of dangers without waiting for the FDA to act."); *id.* at S11835 (statement of Sen. Durbin) ("The drug labeling provisions in today's legislation include a rule of

confirm Congress' intention that, when a manufacturer fails to uphold this responsibility, it should be held accountable under the state tort system, consistent with longstanding practice.

C. The FDA's Longstanding Position Was Consistent With Congress' Understanding.

Until recently, the FDA shared Congress' understanding of the preemptive scope of the FDCA. The FDA has traditionally taken the view that its approval of a drug label does not preempt state laws except in very limited circumstances.

In 1974, for example, FDA adopted a regulation providing for confidential treatment of any identifying information relating to physicians (and other health care professionals) included in adverse drug reaction reports (ADRs) submitted by the manufacturer to the FDA. 21 C.F.R. § 314.80(h). FDA adopted this regulation precisely because it recognized that federal law permits products liability lawsuits in which plaintiffs' counsel would seek such identifying data:

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construction that makes clear that Congress does not intend to preempt state requirements regarding drug companies' responsibilities. Rather, this legislation recognizes that State liability laws, including liability laws for improper drug labeling, play an essential role in ensuring that drug products remain safe and effective for all Americans."). Even those who did not agree with Congress' approach recognized that the FDAAA undermined any argument of preemption. *Id.* at S11837 (statement of Sen. Allard) (expressing disappointment in the Senate's acquiescence to the House language, contained in the Rule of Construction, and warning that it will "open the floodgates" to litigation and is "a definite boon to trial lawyers").

> Large numbers of requests are received from plaintiff's attorneys in product liability lawsuits, requesting records relating to any other injuries caused by the product that is the subject of the lawsuit.

39 Fed. Reg. 44629 (Dec. 24, 1974).

In a 1979 preamble accompanying a drug rule, the agency explained that state tort law does not interfere with federal regulation: "It is not the intent of the FDA to influence the civil tort liability of the manufacturer." 44 Fed. Reg. at 37437 (1979).

Similarly, in a 1998 Final Rule relating to labeling provided directly to patients for certain prescription drugs and other biological products, the FDA indicated that its regulations do not preempt state failure-to-warn claims:

> Some comments contended that the provision of patient labeling would adversely affect the legal liability of manufacturers, physicians, pharmacists, and other prescribers or dispensers of prescription drug products by abrogating the "learned intermediary doctrine." Some comments urged that FDA provide for Federal preemption of State regulation with respect to civil tort liability claims and other labeling requirements. The comment claimed that without preemption, FDA would encourage "failure to warn" claims and challenges to patient labeling, especially compared to professional labeling.
>
> Tort liability cannot be a major consideration for FDA which must be guided

> by the basic principles and requirements of the act in its regulatory activities. Nevertheless, FDA does not believe this rule would adversely affect civil tort liability....
>
> * * *
>
> FDA does not believe that the evolution of state tort law will cause the developments of standards that would be at odds with the agency's regulations.

63 Fed. Reg. 66378, 66384 (1998). FDA added that its regulation providing for FDA approval of patient labeling for a limited number of products was "not intended to preclude the states from imposing additional labeling requirements." *Id.*

In 1986, a former chief counsel of the FDA explained the agency's view that federal approval did not bar state failure-to-warn claims:

> In a number of cases, state and federal courts have held that package inserts approved by FDA have contained inadequate disclosure of risks. … Is not such review under state law a violation of the supremacy of federal law? Are not manufacturers being held liable for inserts controlled not by them but by FDA, so that juries are imposing on manufacturers disclosure obligations inconsistent with the regulation of inserts by FDA? The answer currently is no. In some situations, FDA has not, at the relevant time, considered the precise question of whether the insert it had previously approved should be changed in light of subsequent information. Where that is the case, there would seem to be no

> relevant federal decision entitled to supremacy. Nor does the Food, Drug, and Cosmetic Act reflect a congressional intent to preempt in all circumstances common law review of drug labeling.

Richard M. Cooper, *Drug Labeling & Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG & COSM. L.J. 233, 234-35 (1986).

Another chief counsel of the FDA explained that this Court's no-preemption ruling in *Lohr* was consistent with the FDA's "longstanding ... presumption against preemption." Margaret Jane Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 10 (1997). She added that:

> Given the harsh implications of foreclosing all judicial recourse for consumers injured by defective medical devices, FDA does not believe that Congress intended to effect so sweeping change without even a comment. Rather, the agency believes that Congress intended to restrict preemption to positive enactments (for example, legislation or regulations) that apply to the marketing of medical devices within a state, and did not intend to preempt state tort remedies for injury to individual consumers.

Id. at 9. Although the article concerned medical devices specifically rather than pharmaceuticals, its explanation of FDA's longstanding view of limited preemption applies *a fortiori* with respect to drugs. After all, the FDCA contains no express preemption

provision for drugs, in contrast to the Medical Device Act amendments interpreted in *Medtronic.*

In December 2000, the FDA proposed a new regulation to address the form and content of drug labeling, the principal purpose of which was to require a "Highlights" section on drug labels. At that time, the agency explained that "this proposed rule does not preempt state law," and "FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." 65 Fed. Reg. 81082, 81103 (2000).

In 2006, in finalizing these labeling rules, the agency took a different view with respect to the *very same regulation*, claiming that the federal approval of drug labeling may preempt a state tort claim based on a failure to warn:

> FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.

71 Fed. Reg. 3922, 3934 (2006). FDA added:

> State law actions also threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.

Id. at 3935.

The preemption preamble is an improper FDA power grab that seeks to seize authority belonging to Congress, the States, and the courts. The FDA did an inexplicable about-face and attempted to achieve

federal preemption "through the back door." *Zyprexa,* 489 F.Supp.2d at 275-76. "Until January 24, 2006, the FDA itself had consistently recognized that state-law claims could coexist with federal regulation of prescription drugs: Indeed, the FDA's current position on preemption represents a significant departure from well-settled administrative and judicial views on the issue, and ultimately is both unpersuasive and untenable . . . ." *In re Vioxx Prods. Liab. Litig.,* 501 F. Supp. 2d 776, 788 (E.D. La. 2007).

The 2006 preemption preamble is also inconsistent with Executive Order No. 13132, which requires federal agencies to consult with state and local officials whenever a proposed rule contains preemption provisions. The FDA failed to follow the prescribed procedures in 2006. *See Senate Regulatory Preemption Hearing* at 6-7 (statement of Hon. Donna Stone, Del. State Rep. and President, National Conference of State Legislatures). Accordingly, the Conference of State Chief Justices adopted a resolution in January 2008 stating that "recent actions by federal agencies have led to a growing concern by the Conference of Chief Justices about federal regulatory agency efforts to preempt federal and state statutes and common law through the promulgation of proposed rules."[11]

Even assuming that it would be proper for a court to defer to an agency on the issue of a statute's preemptive effect – an issue which this Court has not resolved[12] – the FDA's new-found position does not

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[11] Available at http://ccj.ncsc.dni.us/FederalismResolutions/resol1Respect PrinciplesOfFederalism.html.

[12] *Smiley v. Citibank,* 517 U.S. 735, 744 (1996); *see also Medtronic, Inc. v. Lohr,* 518 U.S. 470, 512 (1996) (O'Connor, J.,

deserve judicial deference. In fact, in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), this Court did not rely upon the agency's view of the preemptive effect of the Medical Device Amendments. Instead, this Court opined that "the degree of deference might be reduced by the fact that the agency's earlier position was different." *Id.* at 1009. This Court has repeatedly held that an agency's change of position is not entitled to deference. *See*, *e.g.*, *Bates v. Dow Agrosciences LLC,* 544 U.S. 431, 449 (2005); *Norfolk Southern Ry. Co. v. Shanklin,* 529 U.S. 344, 356 (2000); *Good Samaritan Hosp. v. Shalala,* 508 U.S. 402, 418 (1993) (citing *INS v. Cardoza-Fonseca,* 480 U.S. 421, 446, n.30 (1987)).

Further features of the 2006 preemption preamble preclude *Chevron* deference. Because the proposed rule had stated that *no* preemption would arise from the labeling requirement, the public received no notice or opportunity to comment against preemption. The 2000 preamble had addressed preemption not as a subject for comment, but as part of the analysis of the labeling rule itself and whether it ought to be changed because of liability concerns. The 2000 preamble, in other words, presupposed the potential for liability under state law and did not even hint that federal preemption was on the horizon. *See* Content and Format of Labeling for Human Prescription Drugs and Biologics, 65 Fed. Reg. at 81103 (2000). The drafters of the 2006 preamble proceeded from precisely the opposite premise, denying fair notice and an opportunity for interested parties to comment. The absence of public comment

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concurring in part and dissenting in part, joined by Rehnquist, C.J., and Scalia and Thomas, JJ.).

precludes any claim of deference. *See United States v. Mead Corp.,* 533 U.S. 218, 231 (2001) (denying deference because, among other reasons, the agency ruling was "far removed . . . from notice-and-comment process").

Next, the 2006 preemption statement arose in the context of a regulatory preamble. Under FDA regulations, a preamble to a proposed or final regulation is merely "an advisory opinion," rather than part of the rule itself. 21 C.F.R. § 10.85(d)(1). "An advisory opinion may be amended or revoked at any time after it has been issued," without notice or comment. *Id.* at § 10.85(g). "An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement." *Id.* at § 10.85(j). If an advisory option is not binding in administrative or court proceedings, it cannot be entitled to *Chevron* deference. *See Long Island Care at Home, Ltd. v. Coke*, 127 S.Ct. 2339, 2349 (2007) (agency guideline entitled to only "persua[sive]" rather than "bind[ing]" weight); *Gonzales v. Oregon*, 546 U.S. 243, 256-57 (2006) (interpretive rule not entitled to deference); *Mead,* 533 U.S. at 232 ("interpretive rules ... enjoy no *Chevron* status *as a class*"); *Martin v. Occupational Safety and Health Review Comm'n,* 499 U.S. 144, 157 (1991) (interpretive rules are "not entitled to the same deference as norms that derive from the exercise of the Secretary's delegated lawmaking powers"). *See also Shalala v. Guernsey Memorial Hospital,* 514 U.S. 87, 99 (1995) ("interpretive rule" "do[es] not require notice and comment").

In sum, the FDA's 2006 change of position provides no basis for upsetting Congress' longstanding understanding of the preemptive effect of the FDCA. The FDA's abrupt change in view should be rejected.

D. This Court Should Not Upset Congress' Settled Expectations.

Congress, the FDA, and the courts have long assumed the availability of state-law damages actions for failure-to-warn and inadequate warning claims, notwithstanding FDA approval of a drug label. To find preemption in this context would eliminate all compensation for often devastating injuries – lost wages, medical costs, and other traditional forms of damages – without providing any federal remedy as a substitute. It would effectively bestow an immunity on drug manufacturers that Congress has refused to grant.

Moreover, a holding of preemption would also have serious implications for institutional principles arising from the separation of powers. Agencies, as creatures of their organic statutes, do not have the power to regulate with the force of law unless Congress has delegated that power to them. *See Gonzales*, 546 U.S. at 255-56. Deference is warranted only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *Mead*, 533 U.S. at 226-27.

Congress has not authorized the FDA to imbue the 2006 preamble with preemptive force. To defer to the FDA's preemption preamble would turn the

proper inquiry upside down. Preemption is ultimately a question of congressional intent, not agency intent. *Medtronic,* 518 U.S. at 485. An agency may not expand the preemptive reach of a statutory scheme outside the congressional mandate. *See Adams Fruit v. Barrett*, 494 U.S. 638, 650 (1990) (declining to defer to agency's view regarding preemptive reach of federal statute's right of action, and noting that, despite agency's authority to issue relevant safety standards, "an agency may not bootstrap itself into an area in which it has no jurisdiction.") (quoting *Federal Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 745 (1973)).

In addition, important issues of repose and settled statutory meaning counsel strongly against overturning decades of practice under the FDCA. Where Congress, the FDA and the courts have all operated on the basis of a common, longstanding view regarding the construction of a statutory scheme, there are powerful reasons not to disrupt their shared interpretation. The expectations regarding the preemptive effect of the FDCA reflect precisely the kind of "well-embedded interpretation" of a statute that this Court has held is entitled to judicial respect. *CBOCS West,* 128 S.Ct. at 1958.

The value of repose in this context is akin to the principle of statutory *stare decisis.* This Court has explained that it "give[s] great weight to *stare decisis* in the area of statutory construction," in part because of "institutional concerns about the relationship of the Judiciary to Congress." *Neal v. United States,* 516 U.S. 284, 295 (1996) (Kennedy, J.). *See also Hohn v. United States*, 524 U.S. 236, 251 (1998) ("Considerations of *stare decisis* have special force in

the area of statutory interpretation . . . .") (quoting *Patterson v. McLean Federal Credit Union*, 491 U.S. 164, 172-73 (1989)); *Quill Corp. v. North Dakota*, 504 U.S. 298, 320 (1992) (Scalia, J., concurring in part and in the judgment) (stressing importance of *stare decisis* in dormant Commerce Clause context, where Congress "has the final say over regulation of interstate commerce").

For more than 70 years, Congress has operated against the background understanding that FDA approval of a drug label does not bar state-law failure-to-warn claims. If that rule of law is to be altered, it should be changed directly by Congress. This Court should not nullify more than 70 years of practice under the FDCA by bestowing an immunity that Congress has thus far declined to grant, nor should it permit the FDA to accomplish such a result indirectly through an unauthorized expansion of its regulatory power.

E. Preemption Would Disrupt The Congressional Drug Safety Scheme

The congressionally designed scheme for drug safety contemplates a meaningful role for state-law tort actions. When a drug is approved, the available information is not sufficient to guarantee its safety over time. FDA typically approves drugs on the basis of relatively small clinical trials, which may involve healthy volunteers and other subjects far different from the patients for whom doctors usually write prescriptions. The Institute of Medicine of the National Academies reports that drugs are generally tested on no more than 600 to 3,000 patients prior to approval. *See* IOM Report, *supra*, at 36. At the time of approval the label contains only the information

that can be definitively established by the trials. Thus, "FDA approval does not represent a lifetime guarantee of safety and efficacy," and drugs enter the U.S. market with "incomplete safety profiles." *Id.* at 2, 37. Because of statistical limitations, latency periods, and population sub-groups with special characteristics, pre-approval testing cannot reveal the safety problems that may emerge only after long-term, large-scale use. The IOM concluded:

> Preapproval trials typically are too small to detect even significant safety problems if they are rare. An adverse event (even a serious one) that occurs in less than one in 1,000 patients cannot be reliably detected except in the largest premarket trials but can pose a serious public health problem when hundreds of thousands or millions of people use the drug.

IOM Report at 37-38 (citations omitted).

Many features of drug testing, production and marketing can result in new and unexpected risks once a drug enters widespread use, and these dangers are often solely within a manufacturer's knowledge. As a matter of both resources and statutory responsibility, manufacturers are in a far better position than FDA to discover unexpected risks of their own drugs and to make appropriate warnings to patients. FDA oversees the safety of 12,000 drugs made by 5,000 manufacturers around the world. Given the agency's limited resources and information, it is utterly unrealistic to expect that the FDA alone – with no assistance from state tort suits – can protect patients from the post-market risks of even a fraction of these products.

The voluntary physician reporting system on which FDA relies for collecting real-time information on drug side effects identifies fewer than 1% of serious side effects.[13] Moreover, FDA's system for collecting and analyzing those reports is severely antiquated, underfunded, and often overwhelmed, resulting in "incredible missed opportunities" to detect signals of post-market drug risks. *FDA Science & Mission at Risk* at 50 & App. J. A long series of congressional hearings and reports has documented that the FDA's resources are not commensurate with the agency's enormous task.[14] One of FDA's own advisory committees concluded that "[i]n contrast to previous reviews that warned crises would arise if funding issues were not addressed, recent events and our findings indicate that some of those crises are now realities and American lives are at risk." *FDA Science & Mission at Risk* at 6. The committee documented a litany of FDA shortcomings:

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[13] FDA Medwatch, The Clinical Impact of Adverse Event Reporting (Oct. 1996). http://www.fda.gov/medwatch/articles/medcont/postrep.htm#und

[14] *See, e.g.*, *Risk and Responsibility: The Roles of the FDA and Pharmaceutical Companies in Ensuring Safety of Approved Drugs, Like Vioxx: Hearing Before the House Comm. on Government Reform*, 109th Cong. (2005); *FDA's Drug Approval Process: Up to the Challenge?: Hearing Before the Senate Comm. on Health, Educ., Labor and Pensions*, 109th Cong. (2005); *FDA, Merck and Vioxx: Putting Patient Safety First?: Hearing Before the Senate Comm. on Finance*, 108th Cong. (2004); U.S. GOV'T ACCOUNTABILITY OFFICE, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 10, *available at* www.gao.gov/cgi-bin/getrpt?GAO-06-402.

> We found that FDA's resource shortfalls have resulted in a plethora of inadequacies that threaten our society - including, but not limited to, inadequate inspections of manufacturers, a dearth of scientists who understand emerging new technologies, inability to speed the development of new therapies, an import system that is badly broken, a food supply that grows riskier each year, and an information infrastructure that was identified as a source of risk in every Center and program reviewed by the Subcommittee. We conclude that FDA can no longer fulfill its mission without substantial and sustained additional appropriations. . . .

Id. at 2.

The FDAAA of 2007 is intended to address these deficiencies, but it is not a panacea. Even with the enactment of the 2007 amendments, "drugs with unrecognized toxicity will reach the market." Bruce M. Psaty & David Korn, *Congress Responds to the IOM Drug Safety Report - In Full,* 298 JAMA 2185, 2187 (Nov. 14, 2007). Senator Kennedy, chief Senate sponsor of the FDAAA and a leader on federal drug regulation for decades, has explained that even a strengthened FDA should not be expected to assume exclusive responsibility for collecting and analyzing post-market safety data:

> Clearly, the resources of the drug industry to collect and analyze postmarket safety data vastly exceed the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does. It is

> absurd to argue that the FDA, even with the enhanced resources and authorities provided by this legislation, commands the field when it comes to postmarket safety. The drug companies have the capacity to do a far more comprehensive job . . . [and] cannot be allowed to ignore their responsibilities and wait for the FDA to act.

153 Cong. Rec.S11832 (daily ed. Sept. 20, 2007).

By necessity, manufacturers play a central role in the development and dissemination of information about their products. Accordingly, cases brought by injured consumers under state law can help ensure that manufacturers have the incentive to provide the most up-to-date warning information. Gregory Curfman, executive editor of the New England Journal of Medicine, recently warned that "preemption of common-law tort actions against drug and medical device companies is ill advised and will result in less safe medical products for the American people." *House FDA Preemption Hearing* (testimony of Dr. Curfman). Another expert advised a House Committee that:

> Preempting lawsuits against pharmaceutical manufacturers would remove a check on pharmaceutical manufacturers that is essential to prescription drug safety and the public health. Without the possibility of litigation against manufacturers and their executives, we are likely to see greater misrepresentation of safety-related data and more inappropriate use of potentially harmful medications.

Id. (testimony of Aaron S. Kesselheim, Brigham & Women's Hospital and Harvard Medical School).

State tort cases also provide an invaluable source of data for regulators. Time and time again, problems with long-term use of drugs were identified first in failure-to-warn litigation, involving such drugs as Vioxx, Bextra, Celebrex, Avandia, Rezulin, Baycol, Halcion, and Zomax. State court litigation plays the same complementary role in the FDCA context as it does in other areas. *See Bates,* 544 U.S. at 451 ("Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA."); *CSX Transp., Inc. v. Easterwood,* 507 U.S. 658, 668 (1993) (railroad safety); *Hillsborough County v. Automated Medical Laboratories, Inc.,* 471 U.S. 707, 720-21 (1985) (blood plasma).

Moreover, it is clear from the brief *amicus curiae* of the United States in this case ("SG Br.") that in fact there is no conflict between FDA approval of a label and state-law failure-to-warn duties. The Solicitor General explains that, under the FDA's regulations, a manufacturer may make changes in drug labeling by first submitting a supplemental application to the FDA. SG Br. 3. A manufacturer is *required* to submit such a supplemental application "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug." 21 C.F.R. § 201.57(c)(6). FDA labeling regulations instruct that drug "labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug...." *Id.* at §§ 201.57(e), 201.80(e).

The Solicitor General adds that a manufacturer may "change a drug's labeling after its supplemental application is received by FDA, *without waiting for the agency's approval of the change*, if, among other things, the change 'add[s]' or 'strengthens' a warning or a statement about administration of the drug in order to promote safety." SG Br. 3 (emphasis added and quoting 21 C.F.R. § 314.70(c)(6)(iii)(A) and (C)). However, an FDA proposed rule would permit changes without prior approval "only to address 'newly discovered risks' for which there is sufficient evidence of causal association with the drug." *Id.* at 4.

In the view of the undersigned Members of Congress, the FDA's current regulations appropriately require manufacturers to warn of risks as early as possible – regardless of whether the risk is "newly discovered" or not. In any event, even if prior FDA approval for labeling changes to enhance safety were required, such a requirement could not possibly shield a manufacturer from liability (if it could have any preemptive effect at all) when the drug maker had never even requested the approval. In addition, manufacturers may provide risk information by various means *besides* label changes, such as "Dear Health Care Professionals" letters. 21 C.F.R. § 200.5; 44 Fed. Reg. 37434, 37447 (1979). A manufacturer's failure to use such non-label measures may serve as a basis for imposing state-law failure-to-warn liability.

In sum, there is no basis for reversing 70 years of statutory interpretation and preempting traditional state-law failure-to-warn claims.

CONCLUSION

The judgment below should be affirmed.

Respectfully submitted,

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